Detailed Action

This office action is a response to applicant's communication submitted May 6, 2010 wherein claims 12, 13, 16, 18, 19, 28, 29, and 31 are amended. This application is a National stage application of PCT/EP04/10469, filed September 17, 2004.

Claims 12, 13, 16-21, 24, and 27-31 are pending in this application. Claim 27 is withdrawn from consideration as directed to non-elected subject matter.

Claims 12, 13, 16-21, 24, and 28-31 as amended are examined on the merits herein.

Applicant's amendment, submitted May 6, 2010, with respect to the rejection of instant claims 12, 13, 16-18, and 28-30 under 35 USC 103(a) for being obvious over Takahashi et al. in view of Bombardelli et al. in view of Merck, has been fully considered and found to be persuasive to remove the rejection as the claims have been amended to require methyl mannooligosaccharides that are not disclosed by the reference. Therefore the rejection is withdrawn.

Applicant's amendment, submitted May 6, 2010, with respect to the rejection of instant claims 19 and 20 under 35 USC 103(a) for being obvious over La Droitte et al., has been fully considered and found to be persuasive to remove the rejection as the claims have been amended to require methyl mannooligosaccharides that are not disclosed by the reference. Therefore the rejection is withdrawn.

Applicant's amendment, submitted May 6, 2010, with respect to the rejection of instant claim 21 under 35 USC 103(a) for being obvious over La Droitte et al. in view of Tuohy et al., has been fully considered and found to be persuasive to remove the rejection as the claims have been amended to require methyl mannooligosaccharides that are not disclosed by the reference. Therefore the rejection is withdrawn.

Applicant's amendment, submitted May 6, 2010, with respect to the rejection of instant claim 31 under 35 USC 103(a) for being obvious over Lee et al. in view of Lesens et al., has been fully considered and found to be persuasive to remove the rejection as the claims have been amended to require casein glycomacropeptides which are not disclosed in either reference. Therefore the rejection is withdrawn.

Applicant's amendment necessitates the following new ground of rejection:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Isoda et al. (US patent 5260280, cited in PTO-892)

Isoda et al. discloses a compound for neutralizing bacterial toxins caused by *V. cholerae*, *E. coli*, and *Salmonella*. (column 1 lines 60-68) Kappa-casein glycomacropeptide is disclosed as a preferred enterotoxin neutralizer. (column 2 lines 62-65) Amounts of the standard dose of the toxin neutralizer can vary depending on the toxin being neutralized. (column 3 lines 27-35) *V. cholerae*, *E. coli*, and *Salmonella* are describes as causative agents for food poisoning and diarrheal disease. (column 1 lines 14-34) In several examples (examples 1-3 from column 5 line 58 - column 7 line 25) different therapeutic compounds including glycoomacropeptide are tested for the treatment of diarrhea in enteric bacterial infections in 20g mice. Glycomacropeptide at a dose of 1 mg/day, or 50 mg/kg, was fully effective in suppressing diarrhea. The equivalent dose in a 50-75 kg human subject would be 2.5-3.75 g/day. Active agents according to the invention are disclosed in pharmaceutical tablets or solutions for injection. (column 7 lines 27-42) Isoda et al. does not specifically disclose a method of administering between 1-15g of casein glycomacropeptide to a subject suffering from an enteric bacteria associated disorder.

It would have been obvious to one of ordinary skill in the art at the time of the invention to administer the claimed amount of casein glycomacropeptide to a subject suffering from enteric infection with *V. cholerae*, *E. coli*, or *Salmonella*. One of ordinary skill in the art at the time of the invention would have been motivated to administer this compound to treat these disorders because Isoda et al. specifically discloses that these compounds can inhibit diarrhea caused by these organisms. Furthermore, regarding the specific dose range of 1-15g, one of ordinary skill in the art would have been able to determine the optimal dosage level at which to administer the casein glycomacropeptide, particularly by comparison to the effective dose of 50 mg/kg shown in the examples, and would have reasonably expected success as dose optimization is within the ordinary and routine level of skill in the art.

Regarding the limitation that the composition comprise less than 1000 kcal, 1000 kcal is equivalent to about 250g of carbohydrate or 100g of fat. Any reasonable pharmaceutical dosage form such as a tablet, solution, suspension, or the like will be much smaller than these values and will therefore necessarily comprise less than 1000 kcal. Therefore it would have been obvious to one of ordinary skill in the art to make the dosage form as small as is reasonably possible, and to arrive at a dosage form which would comprise less than 1000 kcal.

Therefore the invention taken as a whole is *prima facie* obvious. Because Applicant's amendment necessitated this new ground of rejection, the rejection is made **FINAL**.

Conclusion

Claim 31 is rejected. Claims 12, 13, 16-21, 24, and 28-30 are seen to be allowable. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIC S. OLSON whose telephone number is (571)272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric S Olson/
Examiner, Art Unit 1623
6/9/2010